UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,

Plaintiff,

- against -

CORERX, INC.,

Defendant.

21-cv-10656 (JGK)

OPINION AND ORDER

JOHN G. KOELTL, District Judge:

The plaintiff, Bionpharma Inc. ("Bionpharma"), brought this action against the defendant, CoreRx, Inc. ("CoreRx"), for breach of contract and declaratory judgment. The plaintiff now moves for a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, seeking to compel the defendant to supply the plaintiff with enalapril maleate oral solution in accordance with the parties' Master Manufacturing Supply Agreement. ECF No. 8. Specifically, the plaintiff seeks to compel the defendant to fulfil the remainder of an order that was previously due in December 2021 and to fulfil an additional order that was placed on December 3, 2021 — the total of which constitutes approximately 18,000 bottles of enalapril maleate oral solution.

For the reasons that follow, the plaintiff's motion for a preliminary injunction is **granted.**

I.

The following constitutes the Court's findings of fact and conclusions of law.

"Bionpharma is a generic pharmaceutical company, founded in 2014 to develop and commercialize affordable, quality generic drugs." Krishnan Decl. ¶ 4, ECF No. 10.[1] "Bionpharma's business model is to partner with pharmaceutical manufacturers." Id. Under the terms of these partnerships, the pharmaceutical manufacturers manufacture the drugs, while Bionpharma bears responsibility for sourcing active ingredients, obtaining regulatory approval of the product from the Federal Drug Administration ("FDA"), and selling and distributing the drug product under the Bionpharma label. Id.

"CoreRx is a pharmaceutical Contract Development Manufacturing Organization." Damani Decl. ¶ 5, ECF No. 33. "On behalf of its pharmaceutical customers, CoreRx develops and manufactures clinical trial and commercial drug products." Id.

Bionpharma and CoreRx began doing business together in around 2017. Id. ¶ 10. At some point during their relationship, Bionpharma engaged CoreRx to conduct research and development for a new enalapril maleate oral solution product (the "Product") that Bionpharma would market as a generic version of

[1] Unless otherwise noted, this Opinion and Order omits all alterations, citations, footnotes, and internal quotation marks in quoted text.

the branded drug "Epaned," a product then-owned by Silvergate Pharmaceuticals ("Silvergate"). Krishnan Decl. ¶ 5. Epaned is now owned by Azurity Pharmaceuticals ("Azurity"), CoreRx's sister company. Id.; Marinelli Decl. ¶ 4, ECF No. 11.

In August 2018, Bionpharma submitted an Abbreviated New Drug Application ("ANDA") to the FDA, seeking regulatory approval to market the resulting Product. Krishnan Decl. ¶ 5. In December 2018, Silvergate sued Bionpharma in the United States District Court for the District of Delaware, alleging patent infringement on the basis of Bionpharma's submission. Id. ¶ 7; see also Compl. ¶ 11, ECF No. 1. Silvergate or Azurity brought additional patent infringement lawsuits against Bionpharma in June 2019 and September 2020. Krishnan Decl. ¶ 9. Thus far, none of these lawsuits have been successful, but on April 29, 2021, Judge Stark held that Bionpharma's Product did not violate Epaned's patents. See Silvergate Pharms., Inc. v. Bionpharma Inc., No. 18-cv-1962, 2021 WL 1751148 (D. Del. Apr. 29, 2021).

As this flurry of patent litigation was ongoing, Bionpharma engaged CoreRx to manufacture Bionpharma's Product for commercial sale. Krishnan Decl. ¶ 6. On or around November 24, 2020, Bionpharma and CoreRx executed a Master Manufacturing Supply Agreement (the "Agreement") concerning Bionpharma's Product. Id.; see also Krishnan Decl. Ex. F, ECF No. 10-1 ("Agreement"). As relevant here, the Agreement provides that

"CoreRx shall Manufacture and supply to [Bionpharma], and [Bionpharma] shall purchase from CoreRx, Product that is ordered by [Bionpharma]." Agreement § 5.1. Section 5.4 of the Agreement clarifies that CoreRx must "accept all Firm Orders for a particular calendar month" with few exceptions, and section 5.5 notes that only Bionpharma can cancel or defer orders. The parties further agreed in section 5.11, entitled "Supply Interruption," that, "[i]f CoreRx is unable to supply any Product ordered by [Bionpharma] . . ., then CoreRx shall use Commercially Reasonable Efforts to remedy the problem or secure an alternative source of supply within a reasonable time."

The Agreement left open the price that Bionpharma would pay CoreRx for manufacturing the Product (the "Transfer Price"). Id. § 6.2. However, the parties agreed that the price would "be established by mutual agreement of the Parties on an annual basis one (1) month prior to the commencement of [Bionpharma's] next fiscal year." Id. Once established, that agreed-upon price would "remain in effect for the applicable fiscal year." Id.

As part of the Agreement, Bionpharma also promised to indemnify "CoreRx, its Affiliates and its and their respective officers, directors, employees, and agents, and their respective successors and permitted assigns" for any intellectual property ("IP") infringement claims that might be brought against CoreRx for manufacturing Bionpharma's Product. Id. § 13.1. The parties

also limited liability, so that "in no event [would] either party . . . be liable to the other party . . . for any punitive, indirect or consequential damages or indirect or consequential losses of any kind, nature or description whatsoever (including economic losses or lost profits)." Id. § 13.5 (original capitalization omitted).

The Agreement was to be "in full force and effect for a period of five (5) years from the commercialization of the last Product." Id. § 14.1. Finally, in the event of a dispute, the parties agreed that they would:

> initially attempt in good faith to resolve any significant controversy, claim, allegation of breach or dispute arising out of or relating to this Agreement (hereinafter collectively referred to as a "Dispute") through negotiations between senior executives of [Bionpharma] and CoreRx. If the Dispute is not resolved within thirty (30) calendar days (or such other period of time mutually agreed upon by the Parties) of notice of the Dispute, then the Parties agree to submit the Dispute to non-binding mediation in an attempt to resolve the Dispute. Unless otherwise mutually agreed by the Parties, only if the Dispute is not resolved through negotiations or non-binding mediation as set forth herein, may a Party resort to litigation.

Id. § 16.7.

On August 17, 2021, after having won the above-mentioned lawsuit against Silvergate in the District of Delaware, Bionpharma commercially launched its Product. Krishnan Decl. ¶ 8. Children suffering from cardiac conditions — specifically, hypertension — became Bionpharma's main customers. Id. ¶ 35.

But Azurity's lawsuits did not end with Judge Stark's holding. In June 2021 and October 2021, Azurity brought additional patent infringement suits against Bionpharma based on Bionpharma's Product. Id. ¶ 9. In one of those cases, Azurity sought an injunction to force Bionpharma to withdraw its Product from the market and to cease selling any new Product, but that injunction was denied. Azurity Pharms., Inc. v. Bionpharma Inc., No. 21-cv-1286, ECF No. 87 (D. Del. filed June 22, 2021). In October 2021, Azurity also brought patent infringement lawsuits against CoreRx, accusing CoreRx of infringing the same patents Azurity asserted against Bionpharma on account of CoreRx's manufacturing of Bionpharma's Product. See Azurity Pharms., Inc. v. CoreRx, Inc., 21-cv-1522 (D. Del. filed Oct. 27, 2021); Azurity Pharms., Inc. v. CoreRx, Inc., 8:21-cv-2515 (M.D. Fla. filed Oct. 26, 2021). "Upon becoming aware of Azurity's lawsuits against CoreRx, Bionpharma immediately offered to indemnify CoreRx under the Agreement." Krishnan Decl. ¶ 11. Bionpharma also offered to help pay for separate counsel that CoreRx wanted to retain in addition to counsel provided by Bionpharma, even though this was not required under the Agreement. Id. Both of Azurity's actions against CoreRx have since been voluntarily dismissed. Azurity, 21-cv-1522, ECF No. 6 (D. Del.); Azurity, 8:21-cv-2515, ECF No. 16 (M.D. Fla.); see also id. ECF No. 45 (Report and Recommendation by Magistrate Judge recommending that

the district court deny Azurity's motion to reopen the case to correct the notice of dismissal).

On November 19, 2021, CoreRx sent Bionpharma a letter discussing pricing for products manufactured by CoreRx for Bionpharma and "demanded to more than double the price" for the Product. Krishnan Decl. ¶ 13; see Krishan Decl. Ex. I, ECF No. 14-2 (sealed). Bionpharma responded that the Transfer Price should remain the same. Krishnan Decl. ¶ 14; see also Krishnan Decl. Ex. J, ECF No. 10-5 & ECF No. 14-3.

On November 30, nine days after it unsuccessfully requested a price increase, CoreRx sent a facsimile message to Bionpharma stating that, "as of December 1, 2021, CoreRx will be unable to supply enalapril maleate for [Bionpharma's] Epaned product. In accordance with section 5.11 of the [Agreement] that addresses Supply Interruptions, CoreRx will work with [Bionpharma] to secure an alternative source of supply for this product." Krishnan Decl. Ex. K, ECF No. 10-6. On December 1, Bionpharma responded that CoreRx had not provided the reason for its purported inability to supply the Product under section 5.11 and advised CoreRx that CoreRx was in breach of the Agreement. Krishnan Decl. ¶ 18; Krishnan Decl. Ex. L, ECF No. 10-7. Bionpharma therefore invoked the alternative dispute resolution procedures provided in section 16.7 of the Agreement and demanded an "immediate meeting between senior executives." Id.

On December 3, 2021, Bionpharma submitted another order with CoreRx for the Product. Krishnan Decl. Ex. N, ECF No. 10-9.

The parties and their counsel met for approximately 30 minutes on December 7, 2021. Krishnan Decl. ¶ 21; Damani Decl. ¶¶ 29-30. During this call, Bionpharma claims that CoreRx refused to provide it with a reason for its inability to supply the Product to Bionpharma in accordance with the Agreement. Krishnan Decl. ¶¶ 21-22. CoreRx also informed Bionpharma that it would not deliver the balance of the pending order due for December delivery, and it would not deliver Bionpharma's December 3 order. Id. ¶¶ 23-24.

"Due to CoreRx's conduct," Bionpharma claims that it has been forced to turn down new orders for the Product. Id. ¶ 25. Bionpharma claims that its reputation in the "small and highly competitive" generic pharmaceutical industry as "an innovative and reliable distributor of generic pharmaceutical products," id. ¶¶ 27-28, will be harmed as a result, id. ¶ 30. Indeed, Bionpharma alleges that "[a] sudden failure to fulfil its customers' orders for Product will reverse any gains made by Bionpharma and will drive its customers to seek to purchase their generic pharmaceutical products from any other of Bionpharma's competitors. Failure to deliver product as ordered is one of the most reputationally damaging events that a generic pharmaceutical distributor could endure." Id. In addition,

Bionpharma notes, because it is already under contract to supply its Product to certain customers, that "[i]f CoreRx's breaching conduct continues, Bionpharma will be in breach of its own contractual obligations to its customers, irreversibly damaging its reputation and goodwill. Bionpharma will further need to provide notice to the FDA of an interruption of the manufacture of the Product likely to lead to a meaningful disruption in the supply of enalapril maleate oral solution pursuant to Section 506C(a) of the Federal Food, Drug, and Cosmetic Act." Id. ¶ 31. Bionpharma claims that it will cost it "hundreds of thousands of dollars, and take at minimum nine months to identify and bring online an alternate source of Product." Id. ¶ 34. Bionpharma will exhaust the inventory it has on hand during this time. Marinelli Decl. ¶ 7.

In addition to arguing that CoreRx's failure to supply it with the Product will harm Bionpharma's reputation and standing in the industry, Bionpharma also argues that the public will be harmed by CoreRx's conduct. Krishan Decl. ¶¶ 35-39. In particular, Bionpharma notes that its generic product is cheaper than Epaned, and that customers will be forced to pay higher prices if its product is forced off the market. Id. Furthermore, because of the process by which prescriptions are filled, if a patient is prescribed Bionpharma's Product, that patient may not be able to secure Epaned in the event his pharmacy is out of

Bionpharma's Product. Id. ¶ 39. Getting a new prescription can be "challenging and time consuming" — not to mention, expensive — "with the result that the patient may not be able to secure a refill of his or her prescription before running out." Id.

Bionpharma brought this action on December 13, 2021. ECF No. 1. On the same day, Bionpharma moved for a preliminary injunction. ECF No. 8. On December 15, the parties agreed to a stand-still pending this Court's decision on the preliminary injunction. ECF No. 25.

II.

"A party seeking a preliminary injunction must ordinarily establish (1) irreparable harm; (2) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; and (3) that a preliminary injunction is in the public interest." New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 650 (2d Cir. 2015). However, the court of appeals has held that courts should hold movants "to a heightened standard where: (i) an injunction is mandatory [as opposed to prohibitory], or (ii) the injunction will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." Id. "Mandatory injunctions, for which the

[heightened] standard is appropriate, are those that disturb the status quo by ordering affirmative relief, while prohibitory injunctions preserve the status quo." Johnson v. Kay, 860 F.2d 529, 541 (2d Cir. 1988) (emphasis added). "The status quo is not the current state of affairs but the last actual, peaceable uncontested status which preceded the pending controversy." DJ Direct, Inc. v. Margaliot, 512 F. Supp. 3d 396, 407 n.5 (E.D.N.Y. 2021) (quoting N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc., 883 F.3d 32, 37 (2d Cir. 2018)), appeal dismissed (July 6, 2021), appeal withdrawn sub nom. DJ Direct, Inc. v. JCB Max LLC, No. 21-239, 2021 WL 3555968 (2d Cir. July 13, 2021). When either condition necessitating the heightened standard is met, "the movant must show a clear or substantial likelihood of success on the merits, and make a strong showing of irreparable harm, in addition to showing that the preliminary injunction is in the public interest." Actavis PLC, 787 F.3d at 650.

Contrary to CoreRx's argument, the heightened standard is inapplicable in this case. Bionpharma seeks to compel CoreRx to provide it with a supply of enalapril maleate oral solution in accordance with the parties' Agreement. Far from "alter[ing] the status quo by doing more than is required by the Agreement," see Tom Doherty Assocs., Inc. v. Saban Ent., Inc., 60 F.3d 27, 35 (2d Cir. 1995), the injunction here would "maintain[] the

situation that would prevail if the contract were properly performed," Velez v. Prudential Health Care Plan of N.Y., Inc., 943 F. Supp. 332, 338 (S.D.N.Y. 1996); see also Vestron, Inc. v. Nat'l Geographic Soc., 750 F. Supp. 586, 591 (S.D.N.Y. 1990). The injunction is therefore better categorized as prohibitory, rather than mandatory. Nor, as CoreRx appears to concede, is there anything about the circumstances of the case or the particular features of the injunction that would make relief irreversible. Cf. Tom Doherty, 60 F.3d at 35. Accordingly, Bionpharma need only make the less burdensome showing required of preliminary injunctions that seek to preserve the status quo. This conclusion, however, "is of little import in this case" because, in any event, Bionpharma has satisfied the heightened standard. See Actavis PLC, 787 F.3d at 651.

There is a further preliminary issue. The parties' Agreement provides that the parties must first attempt to resolve disputes through negotiations or non-binding mediation before they may resort to litigation, and CoreRx argues that this precludes injunctive relief in this case. But the Court is "being asked only to issue an injunction so that the [mediation] can go forward before there is a change in the status quo." See Rex Med. L.P. v. Angiotech Pharms. (US), Inc., 754 F. Supp. 2d 616, 620 (S.D.N.Y. 2010). The court of appeals has approved such preliminary injunctions when in aid of arbitration, noting that

"[a]rbitration can become a 'hollow formality' if parties are able to alter irreversibly the status quo before the arbitrators are able to render a decision in the dispute." Blumenthal v. Merrill Lynch, Pierce, Fenner & Smith, 910 F.2d 1049, 1053 (2d Cir. 1990). This reasoning is equally applicable with respect to mediation. Accordingly, the issue to be decided is whether the plaintiff has shown it is entitled to a preliminary injunction.

For the reasons that follow, Bionpharma has adequately demonstrated that it is entitled to a preliminary injunction.

A. Irreparable Harm

First, Bionpharma has made a strong showing that it will suffer irreparable harm absent an injunction.

"[A] showing of probable irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction." Reuters Ltd. v. United Press Int'l, Inc., 903 F.2d 904, 907 (2d Cir. 1990). "Irreparable harm must be shown by the moving party to be imminent, not remote or speculative, and the alleged injury must be one incapable of being fully remedied by monetary damages." Id. A company's "loss of reputation, good will, and business opportunities" from a breach of contract can constitute irreparable harm. Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 404 (2d Cir. 2004); see also Reuters Ltd., 903 F.2d at 909 ("[I]rreparable harm has often consisted of the loss of customers and the competitive disadvantage that resulted from

a distributor's inability to supply its customers with the terminated product.").

In this case, Bionpharma has made a strong showing that it will suffer irreparable harm absent an injunction. CoreRx is Bionpharma's exclusive supplier, and Bionpharma does not stockpile its Product. While the Product supplied by CoreRx may eventually be replaceable, it will take months to find an alternative supplier. In the meantime, Bionpharma will be completely unable to fulfil orders that it is under contractual obligation to supply, and it will be forced to decline new orders. Both of these consequences will result in substantial injury to Bionpharma's reputation and goodwill in the small generic pharmaceutical industry in which relationships and reputation are paramount.

As the court of appeals has recognized, reputational "injury of this sort is nearly impossible to value." Id. at 908; see also id. at 907-08 ("[T]erminating the delivery of a unique product to a distributor whose customers expect and rely on the distributor for a continuous supply of that product almost inevitably creates irreparable damage to the good will of the distributor." (collecting cases)); Register, 356 F.3d at 404; Angiotech Pharms., 754 F. Supp. 2d at 623. Indeed, depriving a party of "the opportunity to sell an entire line of merchandise," may cause that party to "incur injury to its

goodwill and reputation as a dependable distributor." John B. Hull, Inc. v. Waterbury Petroleum Prods., Inc., 588 F.2d 24, 29 (2d Cir. 1978). This reputational damage is difficult to repair, because even in the event that Bionpharma finds an alternative supplier, "customers may . . . refuse to return to [Bionpharma], because of [its] lack of dependability in supplying its product." Angiotech Pharms., 754 F. Supp. 2d at 623. The court of appeals has held that this is precisely the sort of harm for which monetary damages are inappropriate. As the court of appeals noted in Register, it is "very difficult to calculate monetary damages that would successfully redress the loss of a relationship with a client" — or clients — "that would produce an indeterminate amount of business in years to come." Register, 356 F.3d at 404.

CoreRx's attempts to distinguish this case from those in this circuit in which courts have found irreparable harm based on similar risks of reputational damage are unavailing. First, the fact that the parties agreed in section 13.5 of the Agreement to limit liability for "any punitive, indirect or consequential damages or indirect or consequential losses of any kind, nature or description whatsoever (including economic losses or lost profits)" does not preclude injunctive relief. CoreRx cites to no case to support the proposition that because Bionpharma cannot seek consequential damages from CoreRx, it

follows that such damages may not be a basis for it to obtain injunctive relief against CoreRx. In fact, as Bionpharma points out, the parties' limitation of liability might cut the other way in justifying the need for injunctive relief, because "absent preliminary relief, [Bionpharma's] ability to be made whole after a wrongful [breach] would be seriously jeopardized." See Rockwood Pigments NA, Inc. v. Elementis Chromium LP, 2 N.Y.S.3d 94, 97 (App. Div. 2015). Second, Bionpharma is not precluded from seeking such relief because "nothing in the [Agreement] contemplates injunctive relief or specific performance as a form of remedy." Def.'s Mem. in Opp. 15, ECF No. 32. First, the fact that the Agreement does not preclude such relief, when it explicitly precludes other sorts of relief like consequential damages, can just as easily be interpreted to allow this relief. Additionally, New York's Uniform Commercial Code ("UCC") provides the default position that, absent agreement to the contrary, "[s]pecific performance may be decreed where the goods are unique or in other proper circumstances." N.Y. U.C.C. Law § 2-716; see also N.Y. U.C.C. Law § 1-302.

Finally, CoreRx is incorrect that Bionpharma's claims of irreparable harm are merely conclusory. Bionpharma has produced reliable affidavits swearing to its claimed harm, and Bionpharma

need not wait for the supply of its Product to dwindle before it can demonstrate such harm. See Reuters, 903 F.2d at 908-09.

Therefore, Bionpharma has made a strong showing of irreparable harm in the absence of an injunction. Bionpharma's total and sudden inability to supply its Product will result in reputational harm that is "incalculable in dollars and cents," and to which injunctive relief is particularly suited. Id. at 909.

B. Likelihood of Success on the Merits

Second, Bionpharma has shown a substantial likelihood of success on the merits.

To establish a breach-of-contract claim under New York law, a plaintiff must demonstrate: "(1) the existence of an agreement, (2) adequate performance of the contract by the plaintiff, (3) breach of contract by the defendant, and (4) damages." Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y., 375 F.3d 168, 177 (2d Cir. 2004)

CoreRx disputes the existence of a valid contract between the parties, and also disputes that it is in breach. Because the other elements are not disputed, the Court does not consider them. Ultimately, CoreRx's arguments are unpersuasive.

First, CoreRx rightly appears to concede that the parties entered into a contract when the Agreement was signed in November 2020. It also appears to concede that the Agreement has

not been terminated. Accordingly, there would appear to be a valid contract.

CoreRx argues that the contract is void because "[e]nforcing the Contract in the manner Bionpharma advocates would violate" federal patent laws. Def.'s Mem. in Opp. 10. However, CoreRx's argument is unpersuasive. No court has yet held that Bionpharma's Product violates any federal patents. To the contrary, Judge Stark held that Bionpharma's Product did not violate Silvergate's patent, and Azurity failed in its effort to enjoin Bionpharma from selling the Product. CoreRx has made no effort on this motion to demonstrate that its provision of the Product would violate the patent laws. And CoreRx has pointed to no case holding that a competitor's unsubstantiated allegation that another company's product violates its patents thereby voids that company's contracts.

Notably, Lear v. Adkins, 395 U.S. 653 (1969), on which CoreRx relies, does not support CoreRx's argument that "contracts that frustrate the purposes of the federal patent system are preempted and without force." Def.'s Mem. in Opp. 8. In Lear, the United States Supreme Court considered the more limited, specific question of whether the licensee estoppel doctrine — under which a licensee operating under a licensing agreement was estopped from denying the validity of his licensor's patent in a suit for royalties under the agreement —

should be abrogated. Id. at 656. Balancing the "competing demands of the common law of contracts and the federal law of patents," id. at 668, the Court concluded that the federal interest in promoting challenges to patent validity outweighed the licensor's contract interests, id. at 668-71. Accordingly, the defendant-licensee, Lear, Inc., could defend against the plaintiff-licensor's breach of contract suit by arguing that the patent on which their licensing agreement was based was invalid. Id. Additionally, the Court held that Lear, Inc., was not required to continue to pay royalties, as provided in the contract, while it challenged the patent's validity in the courts. Id. at 671-74. The Court reasoned that "[e]nforcing this contractual provision would give the licensor an additional economic incentive to devise every conceivable dilatory tactic in an effort to postpone the day of final judicial reckoning," and that "the cost of prosecuting slow-moving trial proceedings and defending an inevitable appeal might well deter many licensees from attempting to prove patent invalidity in the courts." Id. at 673. Additionally, "enforcing this contractual provision would undermine the strong federal policy favoring the full and free use of ideas in the public domain." Id. at 674. Lear thus sought to enable challenges to patents by licensees. It did not hold that any contracts to sell products that

allegedly infringe on patents are presumptively void. The other cases cited by CoreRx are similarly unsupportive.

Nor is CoreRx and Bionpharma's Agreement otherwise void for illegality under New York law. While it is true that "New York courts will not enforce illegal contracts," Schlessinger v. Valspar Corp., 686 F.3d 81, 85 (2d Cir.), certified question accepted, 975 N.E.2d 489 (N.Y. 2012), and certified question answered, 991 N.E.2d 190 (N.Y. 2013), no court has yet held that CoreRx's provision of the Product violates any law. CoreRx has failed to make any proffer that would raise doubts as to the legality of the Agreement. Bionpharma has thus sufficiently demonstrated that it has a valid contract with CoreRx.

Second, Bionpharma has sufficiently shown that CoreRx likely breached their Agreement. CoreRx has refused to supply Bionpharma with the remainder of its order due in December 2021, and it has also refused to acknowledge the new order placed by Bionpharma on December 3, 2021 as the Agreement requires. Both of these actions constitute a breach of contract.

CoreRx argues that its failure to fill Bionpharma's orders does not constitute a breach of contract because "CoreRx has acted in the manner prescribed by Section 5.11 of the Contract, which governs 'Supply Interruptions.'" Def.'s Mem. in Opp. 13. But CoreRx has not demonstrated that it is unable to supply the Product ordered by Bionpharma, as required by that provision.

Indeed, there was no hint of such inability when, on November 19, 2021, CoreRx demanded a price increase; CoreRx mentioned an interruption for the first time only after Bionpharma rebuffed its price increase. CoreRx's attorney was also unable to provide this Court with a reason for this purported supply interruption when asked on December 14, 2021. During the hearing before the Court on January 25, 2022, CoreRx's counsel disclosed for the first time that CoreRx had agreed in a confidential settlement agreement with Azurity that Azurity's patent cases against CoreRx would be dismissed, and that CoreRx would be subject to suit if it continued to provide the Product to Bionpharma. Putting aside the validity of such an agreement, it does not demonstrate an inability to produce the Product. CoreRx has failed to demonstrate the applicability of section 5.11, which governs supply interruptions. Section 5.11 does not negate CoreRx's breach.

CoreRx separately argues that its failure to fill Bionpharma's orders does not constitute a breach of contract because the parties had "failed to reach mutual agreement on an annual basis with regards to product pricing," and that there is therefore "no supply agreement in place for [CoreRx] to have even breached." Def.'s Mem. in Opp. 14. But the Agreement says no such thing. The Transfer Price provision's emphasis on "mutual agreement" instead implies that the parties must both

agree as to the price, and that one party may not offer a price increase on a take-it-or-leave-it basis. Cf. Ry. Supply & Mfg. Co. v. Safie Bros. Co., 201 F. Supp. 690, 691 (S.D.N.Y. 1962) (absent terminology to the contrary, "the clause pertaining to price revision permitted the parties to mutually agree upon new terms for subsequent quarters of the year, but their failure to do so did not terminate the contract"). There is no other provision in the Agreement that suggests that a failure to agree on price allows CoreRx to terminate the contract. First, "[i]f it was intended that when a party called for revision of prices, if his proposal was not accepted, the contract would be terminated, it would seem that even businessmen would so provide in the agreement." Id. Second, section 2-305 the UCC provides the default position that, where the price is left to be agreed by the parties and they fail to agree, that failure to agree does not terminate the contract; instead, the parties are bound to a "reasonable price at the time of delivery." N.Y. U.C.C. Law § 2-305(1)(b). There is no basis for CoreRx's argument that the parties' failure to agree on a price increase excuses CoreRx's breach. Bionpharma has adequately shown that it is likely to prove that CoreRx breached their Agreement.

Therefore, Bionpharma has shown a substantial likelihood of success on the merits.

C. Balance of the Equities and the Public Interest

Finally, Bionpharma has made a strong showing that the balance of equities tips in its favor and that an injunction is in the public interest.

In determining whether the balance of the equities tips in the plaintiff's favor and whether granting the preliminary injunction would be in the public interest, the Court "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief, as well as the public consequences in employing the extraordinary remedy of injunction." Yang v. Kellner, 458 F. Supp. 3d 199, 216 (S.D.N.Y.), aff'd sub nom. Yang v. Kosinski, 805 F. App'x 63 (2d Cir. 2020), and aff'd sub nom. Yang v. Kosinski, 960 F.3d 119 (2d Cir. 2020).

In this case, both the balance of equities and the public interest favor granting the preliminary injunction. For the reasons described above, Bionpharma will suffer irreparable harm to its reputation and goodwill absent an injunction. On the other side of the scale, CoreRx argues that it risks being liable for millions of dollars to Azurity if it must continue to abide by the Agreement. Even putting aside the implausibility of the claim that Azurity, CoreRx's sister company, would risk bankrupting CoreRx, CoreRx's claimed harm does not outweigh that of Bionpharma. Bionpharma's Agreement with CoreRx specifically

provides that it will indemnify CoreRx for any costs associated with patent infringement. While CoreRx "doubts" that Bionpharma "has the financial capital to reimburse CoreRx for any meaningful share of a damages award," Def.'s Mem. in Opp. 20 n.3, this conclusory doubt does not suffice to tip the balance of the equities to CoreRx's side. In any event, CoreRx was — or should have been — aware that contracting with Bionpharma to manufacture a generic version of Epaned might expose it to potential liability. That CoreRx may now regret doing so because of "doubts" about Bionpharma's ability to pay — or because of fears of subsequent litigation by Azurity — does not tip the equities in CoreRx's favor.

Moreover, an injunction is plainly in the public interest, and this tips the scales further in Bionpharma's favor. Bionpharma's Product is the generic version of brand-name Epaned. It is cheaper than Epaned, and many insurers cover only Bionpharma's Product. If Bionpharma's Product were to be taken off the market, children — Bionpharma's primary user — and their parents would suffer. CoreRx disputes that Epaned is that much more expensive than Bionpharma's Product. But for families with sick children, even a small price increase can make a significant difference. Moreover, CoreRx does not dispute that forcing families to go through the burden of switching

medications for their children does not serve the public interest.

Against this strong public health interest, CoreRx relies only on the public interests served by adherence to the federal patent laws. But this interest is slight when no court has ever found Bionpharma to be in breach of the federal patent laws.

Given the strong likelihood that CoreRx's conduct will drive Bionpharma's Product — the sole generic alternative to brand-label Epaned — off the market, and the likelihood that ailing patients, and in particular children, will suffer as a result, Bionpharma has made a strong showing that the balance of equities tips in its favor and that an injunction is in the public interest.

CONCLUSION

The Court has considered all of the arguments raised by the parties. To the extent not specifically addressed, the arguments are either moot or without merit. The plaintiff's motion for a preliminary injunction is **granted**. The Clerk of Court is directed to close Docket No. 8.

The parties should immediately begin mediation as provided in their Agreement, and the case is stayed pending such mediation.

The plaintiff should submit a proposed preliminary injunction in two days. The defendant may submit any objections one day thereafter.

SO ORDERED.

Dated: New York, New York
January 27, 2022

John G. Koeltl
United States District Judge